IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

SEPRACOR, INC., *et al.*, Plaintiffs, v. BARR PHARMACEUTICALS, INC., *et al.* Defendants.	)	Western Division No. 5:08-CV-362-H(3)
SEPRACOR, INC., *et al.*, Plaintiffs, v. SANDOZ, INC., Defendant.	)	Eastern Division No. 4:08-CV-89-H(3)
SEPRACOR, INC., *et al.*, Plaintiffs, v. SUN PHARMACEUTICAL INDUSTRIES, LTD., Defendants.	)	Western Division No. 5:08-CV-247-H(3)
SEPRACOR, INC., *et al.*, Plaintiffs, v. SYNTHON PHARMACEUTICALS, INC., *et al.*, Defendants.	)	Western Division No. 5:08-CV-179-H(3)

ORDER

This Cause comes before the Court upon Plaintiffs' "Motion for Leave Under the Protective Order to Advise the FDA of Safety Issues Concerning Sandoz's Proposed Label" [DE-242], to which Defendant Sandoz responded [DE-246]. The motion was referred to the undersigned September 29, 2010, and the matter is ripe for adjudication. For the reasons stated herein, the motion is denied.

Background

The facts of the underlying case are well known to all involved and need not be repeated extensively here. Plaintiffs are the owners of United States Patent No. 5,698,558 (the '558 patent) which covers a method of treating allergies using levocetirizine. Levocetirizine is the active ingrediaent in Xyzal, a medication manufactured by Plaintiffs. Defendant Sandoz filed an Abbreviated New Drug Application (ANDA) with the United States Food and Drug Administration (FDA) seeking approval to market a generic version of Xyzal prior to the expiration of the '558 patent. Although Sandoz's ANDA as originally filed sought approval for treatment of both allergic rhinitis and uticaria, Sandoz subsequently revised its ANDA to delete allergic rhinitis from its proposed label. The proposed label "carving out" allergic rhinitis was the subject of a motion by Plaintiffs to reopen discovery and modify the protective order in this case, which the undersigned granted in part and denied in part in an order entered August 9, 2010. [DE-227]. The August 9 order reopened discovery regarding the proposed label because the undersigned considered it relevant to an induced infringement claim by Plaintiffs. [*Id.* at pp.6-7]. The August 9 order also granted a limited exception to the protective order by allowing Plaintiffs' regulatory professionals and experts to review Sandoz's proposed label. [*Id.* at p.9].

The order accordingly downgraded the confidentiality status of information regarding the proposed label from "Outside Counsel Only" to "Confidential."

Plaintiffs contend their experts have now reviewed the proposed label and have concluded that the proposed deletion of "allergic rhinitis" from the label poses a safety issue. According to Plaintiffs' expert, the proposed label is "misleading" and "could compromise the safe and effective use of the product." [DE-243, p.3]. Plaintiffs seek leave under the protective order [DE-37] to file a Citizen Petition with the FDA in order to "call attention to certain safety issues raised by Sandoz's proposed changes to the prescribing information for its proposed product." [DE-242, p.2]. A Citizen Petition filed with the FDA is available to the public. *See* 21 C.F.R. § 10.20(j). By filing a Citizen Petition, Plaintiffs would disclose information regarding Sandoz's proposed label currently protected as "Confidential" under the terms of the stipulated protective order and the August 9 order. Plaintiffs therefore seek modification of the protective order to file its Citizen Petition with the FDA.

Discussion

As noted in the August 9 order, "[c]ourts have the inherent power to modify protective orders, including protective orders arising from a stipulation by the parties." SmithKline Beecham Corp. v. Synthon Pharmaceuticals, Ltd., 210 F.R.D. 163, 166 (M.D.N.C. 2002). The party seeking modification has the burden of showing good cause. *Id.* The court considers a number of factors in exercising its discretion to modify a protective order, including: "the reason and purpose for a modification, whether a party has alternative means available to acquire the information, the type of protective order which is at issue, and the type of materials or documents which are sought." *Id.*

Here, Plaintiffs contend modification of the protective order is necessary to bring safety concerns to the attaention of the FDA. Sandoz responds that Plaintiffs have failed to articulate the particular harm allegedly arising from the proposed label. The undersigned agrees with Sandoz. As Sandoz correctly notes, the FDA specifically reviews proposed labels submitted with an ANDA for safety and efficacy. *See* 21 C.F.R. § 314.127(a)(7). Plaintiffs have moreover failed to show that the FDA has no other means of evaluating the safety of Sandoz's proposed label than through information and guidance provided by a Citizen Petition. In fact, Plaintiffs already filed a thirty-page Citizen Petition on October 14, 2010, urging the FDA to not "approve any ANDA for levocetirizine that carves-out the allergic rhinitis indications, omitting the safety information in Xyzal's labeling related to allergic rhinitis." [DE-261, Ex. 1, p.1]. Although the Citizen Petition filed by Plaintiffs does not contain the specific information covered by the protective order, the generic information presented nevertheless addresses many of the alleged safety concerns raised by Plaintiffs.

Because Plaintiffs fail to show good cause that modification of the protective order is warranted, Plaintiffs' "Motion for Leave Under the Protective Order to Advise the FDA of Safety Issues Concerning Sandoz's Proposed Label" is hereby DENIED.

DONE AND ORDERED in Chambers at Raleigh, North Carolina this 15th day of November, 2010.

WILLIAM A. WEBB
UNITED STATES MAGISTRATE JUDGE